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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,522

05/02/2005

Istvan Hudak

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1625

466 7590 12/15/2008

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,522	<b>Applicant(s)</b> HUDAK, ISTVAN	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32,36-46,50-57 and 59-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32,36-46,50-57,59-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants amendments to the claims filed 09/23/2008 have been entered. Any objection/rejection from the previous office action filed 05/23/2008 not addressed below has been withdrawn.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/23/2008 has been entered.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32,36-37,39,43-46,50-53,56-57,59 and 61-65 rejected under 35

U.S.C. 102(e) as being anticipated by Porter (US 2002/0165583 A1), for the reasons set forth in the previous office actions filed 11/14/2007 and 05/23/2008.

***Response to Arguments***

Applicant's arguments filed 09/23/2008 have been fully considered but they are not persuasive. Applicants assert that Porter fails to describe a polyurethane dissolved in a solvent or capable of solidifying upon separation from the solvent. Instead applicants argue Porter only refers to polyurethane in terms of its prepolymer components. Applicants further assert that the polyurethanes of Porter are limited to solid materials, polymerized from prepolymers then crosslinked. Thus applicants argue that the claimed invention is distinguished from the formation of polyurethane from liquid pre-polymers. Applicants also assert that Porter does not teach a composition which will not stick to vessel walls.

The examiner respectfully disagrees with the above assertions by applicants. Porter clearly states that one embodiment includes a composition that contains a polymer dissolved in a solvent. See [0087]-[0088]. These compositions as stated by Porter are well known in the art as detailed previously within the same reference. Porter did recite the use of polyurethanes as a material useful in embolization of a vascular site, thus one of ordinary skill in the art would have readily envisaged applicants claimed dissolved polyurethane from the teachings of Porter. Furthermore it is noted by the examiner that applicants are apparently taking the position that a prepolymer of polyurethane formed from smaller chains of polyurethane would not read on their claimed invention, however it is noted by the examiner that a prepolymer is still a polymer. Applicants have not limited the MW of the polyurethane at least within the independent claims to exclude a small polymer or even an oligomer of urethane such as

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the prepolymers of Porter. In regards to applicants functional recitation that the intended use for the composition does not adhere to vessel walls is also not found persuasive. Since the composition of Porter is within the scope of applicants claimed invention it is inherent that the same composition will have the same properties.

Claims 32,36,43-46,50,56-57,59-62 and 65-65 rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (US 5,702,361, cited by applicants).

Evans teaches a method for treating vascular lesions with a non-particular agent and an embolizing composition comprising a biocompatible polymer or pre-polymer (including polyurethane), a biocompatible solvent (preferably DMSO) and a contrast agent (including tantalum, tantalum oxide, barium sulfate and tungsten). See abstract, col 5 lin 23-col 6 lin 64, col 7 lin 57-65 and claims 1,23 and 5. Upon contact with the blood the biocompatible solvent would dissipate from the embolic composition whereupon the biocompatible polymer would precipitate. Evans also teaches kits containing the embolic composition and the reference specifically recited delivery by catheter. See col 4 lin 54-62 and col 4 lin 11-46.

Claims 32,36,43-46,50,56-57,59-62 and 65-65 rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (US 6,342,202, cited by applicants).

Evans teaches compositions for embolizing blood vessels which comprise a polymer (including polyurethane and urethane/carbonate copolymers), a biocompatible solvent (including preferably DMSO) and a contrast agent (including tantalum, tantalum oxide and barium sulfate). See abstract, col 3 lin 41-col 4 lin 10. The polymer was

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selected to be soluble in the biocompatible solvent, easy to deliver (e.g. low viscosity) via catheter or syringe, be compatible with the contrast agent and the resulting precipitate should form a well defined coherent mass. See col 2 lin 34-45. When introduced to a vascular site the biocompatible solvent would diffuse into the blood and a solid precipitate would form. See col 6 lin 21-25. It is noted in the examples that table 1 showed that DMSO was incapable of solvating polyurethane, however the copolymer poly(carbonate-urethane) still reads on applicants claimed polyurethane polymer since the claim in no way suggest the polymer is a homopolymer, thus a copolymer containing polyurethane would anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32,36-46,50-57,59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 2002/0165583 A1), for the reasons set forth in the previous office actions filed 11/14/2007 and 05/23/2008.

Applicants reiterate their arguments above in that Porter does not teach a polyurethane polymer dissolved in a solvent. Applicants also argue that Porter requires anchoring of the polymer to the blood vessel wall.

For the reasons stated above the examiner disagrees with the above assertion by applicants in that Porter does disclose polyurethanes for use in the embolization compositions. Regarding the passages within Porter on anchoring, the examiner does not see this as being the same as sticking such as by an adhesive to a vessel wall,

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instead anchoring means to fixate or fasten which could be done by a myriad of different techniques (blocking or plugging a passage for instance) that would not necessarily involve sticking.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618